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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,759	09/08/2003	David Lewis	48924-01030	1172

7590 12/09/2005

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/657,759

Applicant(s)

LEWIS ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/12/05 has been entered.

Receipt is acknowledged of Amendments and Remarks filed on 09/12/05. Claims 1, 17 and 21 are amended, while no claims are added or cancelled. Accordingly claims 1-23 remain pending.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WU et al (WO 0078286) in view of Lasserre et al (6,296,156).

Wu teaches a medicinal aerosol steroid formulation product with enhanced stability. The steroid is a 20-ketosteroid having an OH group at the C-17 or C-21 position and the aerosol container has a non-metal interior surface which has been found to reduce chemical degradation of such steroids (see abstract). Wu also discloses that steroids, especially 20-ketosteroids, are subject to enhanced chemical degradation,

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when stored in contact with a metal container (particularly the metal oxide e.g.,  $Al_2O_3$  layer that forms on the interior surface of the container) (see page 3). The preferred 20-ketosteroids include budesonide, triamcinolone acetonide, dexamethasone and betamethasone. The most preferred type of container is a conventional aluminum (or aluminum alloy) aerosol canister, the interior surface of which is coated with an inert material, such as spray-coated, baked epoxy-phenolic lacquer. The internal surfaces of metal valve components in contact with the formulation are similarly coated with an inert material. Another preferred coating for the inside of the container is perfluoroethylenepropylene (FEP). The coating is preferably used on all of the metal valve components in contact with the formulation, including the inside and outside of the metering chamber, inside and outside of the bottle emptier and the inside and outside of the valve stem (see page 4). Wu lacks disclosure on the rolled neck canister.

Lasserre et al teaches a mounting device for mounting a valve on a container and a dispenser containing a product under pressure fitted with such a mounting device. The inner surface of the cup which comes in contact with the product is coated with a lacquer or some other inert thermoplastic layer (col. 1, lines 63-65). The container containing a product, particularly a liquid, placed under pressure by a conventional propellant, to be dispensed by actuation of the dispensing valve. The open end of the container is formed by a neck, the said neck having a profile capable of engaging with a portion formed on the said external first mounting means. The neck of the container may be rolled outwards with respect to the central axis of the container or alternatively

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may be rolled inwards with respect to the axis of the container. The neck of the container has an edge bent towards the central axis of the container (col. 4, lines 1-34). The container may be a one-piece aluminum can. The cup is made of plastic, such as polyacetal (col. 4, lines 63-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the teachings of Wu et al on providing a stable aerosol formulation of a 20-ketosteroid by reducing chemical degradation, to have looked in the art for a more specific device with rolled neck to use with the said formulations, as taught by Lasserre with a reasonable expectations of successfully preparing a stable steroid formulation.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 10/290,225 in view of Lasserre et al (6,296,156). The examined claims are drawn to a solution formulation comprising an active agent, a cosolvent, optionally a low volatility agent in an aerosol canister having a rim with rounded edges. The claims of copending Application No. 10/290,225 are drawn to the same formulation without reference to the rim or neck of the canister. Lasserre discloses an aluminum canister for aerosol devices with a rolled neck. Therefore it would have been obvious to implement the canister of Lasserre for the formulations of the instant claims such that a stable formulation with long shelf life is provided.

This is a provisional obviousness-type double patenting rejection.

Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-38 of copending Application No. 10/244,519 in view of Lasserre et al (6,296,156). The examined claims are drawn to a solution formulation comprising an active agent, a cosolvent, optionally a low volatility agent in an aerosol canister having a rim with rounded edges. The claims of copending Application No. 10/244,519 are drawn to the same formulation without reference to the rim or neck of the canister. Lasserre discloses an aluminum canister for aerosol devices with a rolled neck. Therefore it would have been obvious to implement the canister of Lasserre for the formulations of the instant claims such that a stable formulation with long shelf life is provided.

The copending Application No. 10/244,519 has recently been allowed, but is not yet issued.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection. However, Applicant's arguments with regard to the Double Patenting rejections will be addressed, since the said rejections are maintained.

Applicant argues that "the Office Action fails to point out which claims of the copending Applications provide the basis for the rejection". This is not persuasive because "claims of copending Application" refers to all the claims of the copending Application. For Applicant's convenience this has been added. It is also noted that the instant claims are drawn to "formulations" of a steroid, propellant and cosolvent. The claims of the said copending Applications also recite formulations of a steroid, propellant and a cosolvent. The canisters also have inner surface coating. Thus it is considered that using different terminology or wording in a claim does not alter the subject matter being claimed. It is widely accepted that hand held devices such as metered dose inhalers are carried around by the users, e.g. in their pockets or bags and the canister is in an upright and/or inverted position multiple times every day. Furthermore, users are typically encouraged to "shake" the container before each application. Wu and Lasserre are both concerned with the stability of the formulations and both have taught that keeping the solution away from the metal part of the canister


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is a good measure. Coating the metal and rolling the rim outwards help keep the solution away from coming in contact with the metal.

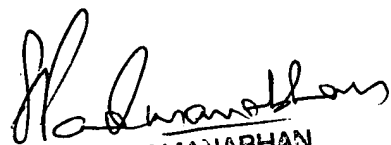
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian  
November 30, 2005



GREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER